

ADOPTED

BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

#29 APRIL 19, 2011



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EXECUTIVE OFFICER

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Board of Supervisors**

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*To ensure access to high-quality,
patient-centered, cost-effective
health care to Los Angeles
County residents through direct
services at DHS facilities and
through collaboration with
community and university
partners*

April 19, 2011

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

**APPROVAL OF AMENDMENT NO. 3 TO ORGAN DONATION SERVICES
AGREEMENT FOR DEPARTMENT OF HEALTH SERVICES
(ALL DISTRICTS)
(3 VOTES)**

SUBJECT

Request approval of Amendment No. 3 to Agreement No. H-210806 with OneLegacy, Inc. to incorporate changes in federal and State laws and regulations which govern the relationships among hospitals, organ procurement organizations, and patients and requests approval of the modification made to the term provision so that it is open-ended.

IT IS RECOMMENDED THAT YOUR BOARD:

Authorize the Director of Health Services (Director), or his designee, to execute Amendment No. 3 (Exhibit I), which reflects changes in federal and State laws and regulations which govern the relationships among hospitals, organ procurement organizations (OPOs), and patients; and which modifies the term of the agreement to be open-ended, or "evergreen."



PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of the first recommendation allows for the current Agreement to be updated to reflect changes in federal and State laws and regulations which govern the relationships among OPOs, hospitals, and patients, thereby ensuring hospital compliance with all current federal and State regulatory mandates with regard to OPOs as they relate to hospitals and patients, thereby ensuring hospital compliance with all current federal and State regulatory mandates with regard to OPOs as they relate to hospitals and patients.

Approval of this recommendation also permits the term provision to be "evergreen." Therefore, the Agreement's term will be open-ended and will terminate only upon one of the following occurrences: (1) OneLegacy is decertified by CMS; (2) another OPO is designated by CMS; (3) a waiver is granted to the County such that it is no longer subject to compliance with any federal or State regulations requiring the County to refer potential organ and tissue donors to any OPO; or (4) the County demonstrates that it is no longer subject to compliance with any federal or State regulations requiring that it refer potential organ and tissue donors to any OPO.

OneLegacy is the federally designated OPO that serves our County hospitals. Medicare Conditions of Participation require that all Medicare-contracted hospitals and their designated OPO have an affiliation in which hospitals will refer all deaths to the OPO in a timely manner and that hospitals collaborate with the OPO to facilitate tissue recovery from patients who may wish to donate their organs, eyes, and tissues upon their death.

Implementation of Strategic Plan Goals

The recommended action supports Goal 4, Health and Mental Health, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

There is no fiscal impact as a result of the recommended action.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

On September 14, 1999, your Board approved Agreement No. H-210806 with Southern California Organ Procurement Center, Inc. (SCOPC), which was the federally designated regional organ procurement organization for Southern California.

On June 29, 2004, your Board approved Amendment No. 1 which extended the term of the Agreement effective July 1, 2004 through June 30, 2007 with OneLegacy, formerly known as SCOPC.

On June 12, 2007, your Board approved Amendment No. 2 to reflect changes in federal and State laws and regulations affecting the relationships among the OPOs, hospitals, and patients; to add Board-mandated provisions; and to extend the term of the Agreement effective July 1, 2007 through June 30, 2012.

County Counsel has reviewed and approved Exhibit I as to form.

CONTRACTING PROCESS

Not applicable.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommended action will ensure Department of Health Services' compliance with federal and State mandates and prevent interruption of organ donation services.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mitchell Katz". The signature is written in a cursive, flowing style.

Mitchell H. Katz, M.D.
Director

MHK:adb

Enclosures

c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

EXHIBIT I

Contract No. H-210806-3

**ORGAN DONATION SERVICES AGREEMENT
AMENDMENT NO. 3**

THIS AMENDMENT is made and entered into this 19th day
of April, 2011,

by and between COUNTY OF LOS ANGELES (hereafter
"County").

and ONE LEGACY, a California non-profit
public benefit corporation
(hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled "ORGAN DONATION SERVICES AGREEMENT", dated September 14, 1999, and further identified as County Agreement No. H-210806, and any amendments thereto (all hereafter referred to as "Agreement"); and

WHEREAS, OneLegacy is an organ, tissue and eye procurement agency, and is designated by the Secretary of Health and Human Services as the organ procurement agency to serve the counties of Los Angeles, Kern, Orange, Riverside, San Bernardino, Santa Barbara and Ventura (the "Donation Service Area"), in accordance with California Health and Safety Code Section 7150.5 *et seq.* or successor statutes, henceforth referred to as the Uniform Anatomical Gift Act ("UAGA"), and federal law and regulations, including 42 C.F.R. §482.45 *et seq.*, henceforth also referred to as the "Medicare Conditions of Participation."

WHEREAS, it is the intent of the parties hereto to amend the Agreement to incorporate additions, revisions, and/or deletions to reflect changes in federal and state laws and regulations that govern the relationship among hospitals, organ and tissue procurement organizations, and patients as described in California Health and Safety Code Chapter 3.5, Section 7150 of Part 1 of Division 7; California Motor Vehicle Code, Section 12811; Centers for Medicare and Medicaid Services' (CMS) rules and standards; The Joint Commission; the Organ Procurement Transplant Network (OPTN); and to make other hereafter described changes; and

WHEREAS, COUNTY is located in the OneLegacy Donation Service Area and is required by state and federal law and regulations, including the Medicare Conditions of Participation to participate in OneLegacy's organ procurement program, in accordance with the UAGA; and

NOW, THEREFORE, the parties agree as follows:

1. This Amendment shall become effective April 19, 2011.
2. The first paragraph of Paragraph 1, TERM, shall be amended as follows:
"1. TERM: The term of this Agreement shall commence on July 1, 2007, and shall continue in full force and effect thereafter."
3. Exhibit A, STATEMENT OF WORK, Paragraphs 1, 2 and 3 shall be deleted and replaced as follows:
"Exhibit A, STATEMENT OF WORK:
1. Identification of Donors: COUNTY shall notify OneLegacy of all potential organ and tissue and eye donors, and in conjunction therewith, further agrees to:

- a. Promptly refer all imminent and cardiac deaths for organ, tissue and eye donation. Timely notification is within one hour of mutually agreed upon clinical triggers pursuant to 42 CFR 482.45 and in 42 CFR 486, subpart G;
- b. Ensure timely and legal documentation of death, signed by COUNTY authorized personnel including a timely confirmation of the initial declaration in cases of death by neurologic criteria “(irreversible cessation of all functions of the entire brain, including the brain stem);” Ensure documentation of death declarations in patient’s medical record with date, time and signature of physicians, when indicated;
- c. Medically manage the patient in order to maintain and maximize the option of organ donation for patients/families prior to the time OneLegacy takes over such maintenance, and cause appropriate documentation to be entered in the Order section of the patient’s medical record of all such donor management activities;
- d. Provide access to and copies of the potential donor's medical record in accordance with federal and state law and Sections 5 and 6 below;
- e. Assist OneLegacy in donor management during the pre-recovery process. Provide 1-1 nursing, under OneLegacy’s protocols, and maintain potential donors while the testing and placement of organs anatomical gift(s) takes place, as medically appropriate;
- f. Work with OneLegacy to create a collaborative team

approach to ensure all families of potential donors within COUNTY are sensitively informed about the gift of organs, tissues or eyes made by their family member's valid document of gift or registration as a donor, both as defined by the U.A.G.A. and Section 12811 of the Vehicle Code, or their option to donate organs, tissue and eyes, whichever is applicable. In accordance with the requirements for designated requestors contained in 42 CFR 482.45, OneLegacy personnel shall bear primary responsibility as the designated/appropriate requestor for approaching the appropriate member of the defined classes who may authorize donation in accordance to California Health and Safety Code 7150.40, collaborating with the COUNTY staff and documenting consent or decline, as well as medical/social history. As appropriate and if specifically requested by COUNTY, OneLegacy will provide annual designated requestor training for qualified COUNTY personnel;

g. Provide an appropriate location, including, as applicable, an operating room or an adequate facility for aseptic recovery of anatomical gifts, and personnel, as needed. Provide access to COUNTY services such as laboratory services, radiological services, cardiology services, anesthesia services, morgue access, and operating room availability on a 24/7 basis. OneLegacy may require urgent access to the operating room in cases when the potential organ donor becomes unstable or family requests impose time constraints;

h. COUNTY hereby designates OneLegacy as its sole tissue recovery agency and engages OneLegacy as COUNTY's tissue and eye recovery agency to fulfill the requirements of 42 CFR 482.45. Changes to this designation may be made only upon one- hundred eighty (180) days written notice to OneLegacy;

i. Work cooperatively with OneLegacy to facilitate continuing education to COUNTY staff on all aspects of organ, tissue and eye donation;

j. With the approval of both parties, designate a key committee to review and improve the donation process, including, but not limited to, the creation of policies and procedures with regard to the recognition of documents of gift as legally binding documents, pronouncement of brain death and After Cardiac Death donation (may also be referred to as Asystolic donation or Donation after Cardiac Death (DCD)). After Cardiac Death donation occurs in situations in which the family or patient desire to withdraw ventilator support, and independent of that decision, the patient/family/document of gift or registration as a donor would like organ donation;

k. Identify one or more staff members to serve as a donation liaison to OneLegacy;

l. Utilize discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors; and

m. Honor the wishes of the decedent to donate organs, tissues and eyes as expressed in a valid document of gift. Pursuant to the UAGA as defined in California Law (CA H&S 7150), and the Motor Vehicle Code (CA MVC 12811), an anatomical gift, that is not revoked by the donor before death, is irrevocable and does not require the consent or concurrence of any person after the donor's death. This includes an anatomical gift that is made by means of and/or is registered in the California Organ and Tissue Donor Registry;

n. To define the respective and joint responsibilities of the OPO and COUNTY and to create a protocol for all families wishing to make an anatomical gift through After Cardiac Death donation in accordance with 42 CFR 486, subpart G and 42 CFR 486.45;

o. To ensure that the electronic simultaneous organ placement process prescribed by the United Network for Organ Sharing (UNOS) is utilized to maximize and expedite the anatomical gift, COUNTY will provide OneLegacy with a wired/wireless secure Internet connection in or near the Critical Care units and Operating Room, in order for OneLegacy to upload donor information to UNOS and simultaneously share that information with prospective transplant centers;

p. COUNTY acknowledges that OneLegacy works through a contracted Call Center, which supports the functions of OneLegacy's Family Care Center. COUNTY further agrees to inform its Staff and

contractors of the Call Center's authority to perform on behalf of OneLegacy.

COUNTY further agrees to inform its Staff and contractors of the Call Center's authority to perform on behalf of OneLegacy.

2. Recovery of Organs/Tissues/Eyes: OneLegacy shall coordinate the retrieval of anatomical gift(s) and in conjunction therewith, further agrees to:

- a. Promptly evaluate all potential donors to determine their medical suitability for organ, tissue or eye donation on a 24/7 basis;
- b. Review each potential donor patient's medical record to ensure documentation of brain death declarations with date, time and signature of two licensed physicians, or, in the case of asystolic donors, ensure appropriate documentation of cessation of heart and respiratory function, as defined by COUNTY policy;
- c. During donation after brain death, OneLegacy will manage the donor during the pre-recovery process under OneLegacy's protocols and procedures. During After Cardiac Death donation, the Attending Physician or designee shall continue to medically manage the patient until cardiac death occurs;
- d. Work with COUNTY on creating a collaborative team approach to ensure all families of potential donors within COUNTY are sensitively informed about the potential donor's decision to donate as documented by valid document of gift, or the family's option to donate, as

applicable. OneLegacy personnel shall bear primary responsibility for approaching the family and documenting informed consent or refusal, as well as medical/social history;

e. Coordinate surgical procedures and personnel for the organ, tissue or eye recovery, including the coordination and provision of an appropriately licensed and otherwise qualified recovery team. In the case of tissue and eye recovery, OneLegacy will coordinate surgical recovery, utilizing trained recovery technicians;

f. If the potential donor is determined to be a coroner's case, OneLegacy will ensure that the coroner or medical examiner has agreed and approved the removal of anatomical gift(s) pursuant to Health and Safety Code, Section 7184.5 and that such approval is documented in the medical record;

g. Preserve, transport and distribute organs for transplantation according to the guidelines established by the Organ Procurement and Transplantation Network, and otherwise facilitate the use of anatomical gift(s) as required by the UAGA. OneLegacy will ensure that proper documentation is prepared for the transplant program about the recovered organ(s) including blood type and other identifying information, and will notify transplant COUNTY of any OPO policy changes that affect placement, labeling and packaging;

h. Provide follow-up communication with the donor family;

- i. Provide continuing education to COUNTY staff on all aspects of donation, including After Cardiac Death donation; and
- j. Utilize discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;
- k. Record promptly and maintain all information pertaining to OneLegacy's performance of duties and services under this Agreement and OneLegacy's records relating to services performed hereunder shall be available to COUNTY upon request, subject to applicable laws and regulations.

3. OneLegacy Organ Surgical Recovery Team Responsibilities

- a. While organ donor management and organ and tissue recovery personnel are not treating living patients and therefore are not required by law to be licensed, OneLegacy shall, at the request of COUNTY, provide COUNTY with any licensing information furnished by the recovery teams, which information shall have been represented by such recovery teams and OneLegacy to be complete and accurate on the members participating in the recovery procedure, unless COUNTY's own surgical organ transplant recovery team is to be utilized.
- b. OneLegacy shall utilize COUNTY's staff physicians to the extent reasonably available, to assist OneLegacy in evaluating potential organ donors to determine their medical suitability for donation. However, when COUNTY's physicians are not available, COUNTY grants OneLegacy permission to consult with licensed and qualified medical professionals of its choice to assist in such evaluation."

4. Paragraph 3.b.(5), DESCRIPTION OF SERVICES, shall be revised to read as follows:

“3.b. (5) DESCRIPTION OF SERVICES: Death Record Review: In order to conduct necessary reviews of records in accordance with the 42 CFR 482.45 and 42 CFR 486 part G, OneLegacy shall have access to review all death records to improve identification of potential donors. This review enables both parties to evaluate and monitor the effectiveness of the services provided and to provide a means to verify, beyond the execution of this Agreement, the compliance with all applicable laws, regulations, and standards relating to the donation of anatomical gift(s). OneLegacy will provide COUNTY with an analysis and evaluation of COUNTY’s organ and tissue donation process.”

5. Paragraph 3.b.(9), DESCRIPTION OF SERVICES, shall be amended to add the following:

“3.b.(9) In the event that COUNTY implements an electronic health records system, COUNTY will provide OneLegacy timely access to patient records to facilitate all aspects of donation and death record reviews.”

6. Paragraph 14, CONFIDENTIALITY, shall be revised to add the following:

“Paragraph 14, Confidentiality: All patient information is considered confidential and each party shall maintain in strict confidence consistent with applicable federal and state law any information disclosed by COUNTY to OneLegacy or an agent of OneLegacy. COUNTY acknowledges that HIPAA, at 45 CFR 164.512(h) allows information to be

released to OPOs or other entities involved in organ and tissue donation and transplantation without patient release. OPOs are not Business Associates of COUNTYs, and do not enter into Business Associate Agreements. In addition, disclosure may occur only under the following circumstances:

- a. Where disclosure is required under any federal or state law or regulation;
- b. Where such information is used for the compilation of statistical data upon request of other organizations. However, in no event shall the parties disclose the name, home address, social security number, names of next-of-kin of a patient, or other patient identifying information for this purpose;
- c. For OneLegacy or IRB approved research projects, if and only if all patient identifiers have been removed, or if the information is subject to a Limited Data Use Agreement between COUNTY and researcher, if applicable.”

7. Paragraph 15, NONDISCRIMINATION IN SERVICES, shall be amended to read as follows:

“15. NONDISCRIMINATION IN SERVICES: The parties mutual agree that, except as provided under acceptable medical and legal criteria, no donor or potential donor shall be unlawfully rejected or otherwise discriminated against on account of race, color, creed, national original, religion, sex or other unlawful reason.”

8. Paragraph 45, DEBARMENT/EXCLUSION FROM STATE OR FEDERAL PROGRAMS, shall be added to Agreement as follows:

“ 45. DEBARMENT/EXCLUSION FROM STATE OR FEDERAL PROGRAMS:

The parties hereby represent and warrant that neither they, their employees nor their principals (if applicable) are presently debarred, suspended, proposed for debarment, declared ineligible, or excluded from participation in any State or federally funded program, including Medicare and Medicaid. The parties each hereby agree to immediately notify the other party of any threatened, proposed, or actual debarment, suspension, or exclusion from any State or federally funded program, including Medicare and Medicaid.”

9. Paragraph 9, COMPLIANCE WITH APPLICABLE LAW, shall be amended to read as follows:

“Paragraph 9, COMPLIANCE WITH APPLICABLE LAW: OneLegacy and COUNTY agree to comply with all federal, state and local laws and regulations which pertain to the performance of this Agreement, including, without limitation, applicable regulations promulgated by OSHA, CMS, OPTN, CDC, and FDA, as applicable. OneLegacy employees are not COUNTY employees or a vendor, therefore, COUNTY has no legal obligation to vaccinate OneLegacy staff.

Furthermore, OneLegacy staff are not COUNTY employees and not required to attend COUNTY orientation or other programs mandated for staff. OneLegacy is solely responsible for maintaining records for OneLegacy employees with regard to job competencies, training, immunizations and medical testing. OneLegacy agrees to work cooperatively with COUNTY with regard to facilitating COUNTY's

demonstrated compliance with those standards of care and quality promulgated by the Joint Commission which applies to the performance of this Agreement. Both parties agree to work cooperatively to implement appropriate changes, correct deficiencies and/or establish policies required and/or recommended by the inspecting agencies.”

10. Paragraph 35, NOTICES, shall be amended as follows:

“Paragraph 35, NOTICES: Any written notices required under this Agreement, or which either party desires to give to the other, shall be in writing and addressed to the other party as follows:

Los Angeles County
Contracts & Grants Division
313 N. Figueroa St., 6th Floor East
Los Angeles, CA 90012
Attn: Director
Facsimile No.: 213-250-2958
Phone No.: 213-240-8205

Los Angeles County Harbor –UCLA
1000 West Carson St.
Torrance, CA 90502-2059
Attn: Chief Executive Officer
Facsimile No.: 213-328-9624
Phone No.: 213-222-2345

High Desert Health System
44900 60th Street West
Lancaster, CA 93536-7621
Attn: Chief Executive Officer
Facsimile No.: 661-945-8474
Phone No.: 661-948-8581

Los Angeles County
Olive View-UCLA Medical Center
14445 Olive View Drive
Sylmar, CA 91342
Attn: Chief Executive Officer
Facsimile No.: 818-364-3011
Phone No.: 818-364-1555

Los Angeles County
University of Southern California Medical
Center
1200 North State St.
Los Angeles, CA 90033
Attn: Chief Executive Officer
Facsimile No.: 323-226-6696
Phone No.: 323-226-2622

Rancho Los Amigos National
Rehabilitation Center
7601 Imperial Highway
Downey, CA 90242
Attn: Chief Executive Officer
Facsimile No.: 562-803-5876
Phone No.: 562-401-7111

Martin Luther King, Jr.
Multi-Services Ambulatory Care Center
12021 South Wilmington Ave.
Los Angeles, CA 90059
Attn: Chief Executive Officer
Facsimile No.: 310-638-8193
Phone No.: 310-668-4321

OneLegacy
221 South Figueroa Street, Suite 500
Los Angeles, CA 90012
Attn: Hospital Services
Facsimile No.: 213-229-5601
Phone No.: 213-229-5634

Any such notice shall be deemed to have been fully given (i) upon delivery, if personally delivered or delivered by any form of airborne/overnight delivery service, (ii) the next business day after confirmation of receipt by the sender's facsimile machine, if transmitted by facsimile and followed immediately with a copy sent by the United States mail first class postage paid, or (iii) two (2) business days after being deposited in the United States mail, certified with return receipt requested and postage prepaid, sent by mail. Either party may change its address by giving notice in the manner provided herein."

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IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its Director of Health Services and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officers, the day, month, and year first above written.

COUNTY OF LOS ANGELES

By _____
Mitchell H. Katz, M.D.
Director

ONELEGACY, a California non-profit public
benefit corporation _____
Contractor

By _____
Signature

Printed Name

Title _____
(AFFIX CORPORATE SEAL HERE)

APPROVED AS TO FORM
Andrea Ordin, County Counsel

ADB:eh